

IN THE DRAWINGS

Please amend Figure 4A, as indicated in the redlined version of the drawings.

Please insert Figures 5A-H, as indicated in the enclosed new version of the drawings.

REMARKS

Claims 1-4, 6-14, 16, 18-19, 25-26 and 37-42 are pending in this application, of which claims 4, 9, 14, 16, 26 and 40 are currently withdrawn from examination pursuant to a previous election, but are to be reinstated and allowed upon allowance of a respective generic (and any intervening) claim from which the respective withdrawn claim depends. Claims 5, 15, 17, 20-24, 27-36 are cancelled. Based on the following remarks, reconsideration, withdrawal of the claims rejection and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement listing references that were cited in related US Patent Application S.N. 10/669,543. Applicant respectfully requests consideration of the references cited in the information disclosure statement.

Drawing Objections

The drawings stand objected under 37 C.F.R. §1.83 (a). The specification and drawings have been amended to show in the drawings the features of the invention recited in the current claims. Figures 5A-H have been added to show the claimed "first material", "bioactive agent" and the "second material" in the coil and on the coating of the coil. Support for the new figures is found throughout the specification. In particular, support for FIGS. 5A-C is found, at least, in the paragraph beginning in line 8, page 6 of the specification. Further support for FIG. 5C is found in the paragraph beginning in line 4, page 7 of the specification. Support for FIG. 5D is found, at least, in the summary of the invention. Support for FIG. 5E is found in the paragraph beginning in line 11, page 8 of the specification. Support for FIGS. 5F-G is found, at least, in the paragraph beginning in line

22, page 8 of the specification. The specification has been amended to correspond to and reference to the new drawings. No new matter has been added. As such, Applicant respectfully requests that figures 5A-H to be entered and withdrawal of the drawing objections.

Claim Rejections - 35 U.S.C. §103

Claims 1-3, 6-8, 10-13, 37 and 39-42 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over U.S. Patent No. 5,853,418 ("Ken") in view of U.S. Patent No. 5,108,407 ("Geremia") and in further view of U.S. Patent No. 6,280,457 ("Wallace"). In particular, the Examiner has asserted that, in view of Geremia and further view of Wallace, it would have been obvious to one skilled in the art to construct the coil device described in Ken with a bioactive agent that is release or activated from the rest of the device by heating. Applicant respectfully disagrees.

Under 35 U.S.C. §103(a), to establish a prima facie case of obviousness of a claim, all of the claim limitations must be taught or suggested, and all words in a claim must be considered in judging the patentability of that claim. In addition, there must be some suggestion or motivation to modify the primary references (in this case, Ken), and a reasonable expectation of success. The mere fact that Ken can be modified does not render the resultant modification obvious to do, unless the reference or some other source (of which none has been presented by the Examiner) also suggests the desirability of making the modification. MPEP § 2146. Applicant respectfully submits that Ken in view of Geremia and further view of Wallace cannot support the §103(a) rejections in view of these requirements.

Ken discloses releasing a vaso-occlusive coil in a treatment site using a well-known electrolytically severable joint (Col 6, lines 38-62). Geremia discloses releasing a vaso-occlusive coil into the treatment site by heating an adhesive bond that joins the coil to the delivery device (Col 4, lines 14-15). Even if Geremia may be properly combined with Ken, such combination would still not teach or suggest that the **coil** of Ken would be made of a material that acts as a heating member when implanted in a treatment site in the patient's vasculature and exposed to an external energy source. Both of these references disclose releasing a coil from a delivery device by detaching a severable joint; neither reference discloses or suggests heating the already implanted coil using a source of energy located external to the body, as recited in independent claims 1 and 37. More particularly, the application of electricity or heat as disclosed in Ken and Geremia respectively, is to a severable **joint that releases the coil** from a delivery device into the treatment site and **not** to the coil itself. In contrast, independent claims 1 and 37 recite that a bioactive agent is released or activated upon heating the device or first material, respectively, after the vaso-occlusive device has been implanted at the treatment site. Independent claim 42 requires that a second material is, at least, partially melted and fused together upon heating of the device after the vaso-occlusive device is implanted at the treatment site to stabilize the vaso-occlusive device.

It was stated in the office action that, in view of Geremia and further view of Wallace, it would have been obvious to construct the coil device described in Ken with a bioactive agent that is detached from the rest of the device by heating. Wallace discloses a vaso-occlusive device comprising an inner core covered with a polymeric fiber, wherein the polymeric fiber covering may be used as a carrier for bioactive molecules (Col 12, lines 4-

14). However, there is no suggestion or motivation that a polymeric fiber cover that may carry bioactive molecules would be desirable in the coil of Ken, absent hindsight in view of the present application. Additionally, Wallace does not teach or suggest that the bioactive agent may be released or activated from the polymer device into the treatment site by application of an external energy source to heat the device after the device has been implanted at the treatment site. Nor does Wallace teach or suggest melting and fusing the material to stabilize the vaso-occlusive device.

For at least these reasons, Applicant respectfully submits that independent claims 1, 37 and 42, as well as claims 2-3, 6-8, 10-13, and 39-41 which depend therefrom, are allowed over Ken, Geremia and Wallace, and requests withdrawal of the §103 claim rejections.

Additionally, claims 7, 18, 19, 25 and 38 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ken in view of Geremia, in further view of U.S. Patent Wallace and *in still further view* of U.S. Patent No. 6,059,815 ("Lee"), a combination of four separate references. In particular, the Examiner has stated that, in view of Geremia, in further view of Wallace, and in still further view of Lee, it would have been obvious to one skilled in the art to construct the coil device described in Ken comprising a ferrous material with a bioactive agent that is detached from the rest of the device by RF and magnetic inducing heating. Applicant respectfully disagrees.

As demonstrated above, neither Geremia nor Wallace may be properly combined with Ken to result in the presently claimed invention, and there is no suggestion or motivation to further combine Lee. Lee discloses an aneurysm occlusion device that is

released by laser, RF or magnetic inductive heating, which, again, **releases the coil** from the delivery device into the treatment site. However, claims 7, 18, 19 and 25 recite the **release of a bioactive agent**, and claim 38 recites the **activation** of a bioactive agent, upon magnetically inducing heating of the device **after it is implanted** at the treatment site.

Additionally, Ken discloses a vaso-occlusive device comprising a helical wound coil with a stretch-resisting member. The stretch-resisting member of Ken may "optionally contain modest amounts of iron." (Col. 5, lines 1-2). However, there is no mention or suggestion in Ken that such "modest amounts of iron" in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to an external energy source (e.g., MR) when the coil is implanted at a treatment site. Nor is there any mention in Ken that the "optional" modest amounts of iron would be embedded in the filament versus applied as a coating, or otherwise. And, in particular, there is no mention in Ken that the coil itself contains, (or may optionally contain), any amount of iron, despite a very detailed description of what materials the coils are made from (Col. 4, lines 47-60).

The cited references, either alone or in combination, do not teach or suggest the construction of the coil device described in Ken with a bioactive agent that is released or activated by the heating the coil with an external energy source after the coil has been implanted. Therefore, Applicant respectfully submits that a prima facie case of obviousness based on the cited references has not been established, and requests that the Examiner reconsider and withdraw the obviousness rejections.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully submits that all pending claims are allowable over the cited references. Accordingly, a notice of allowance is earnestly solicited. If the Examiner believes that a further telephone interview could expedite resolution of any remaining issues, he is welcome to call the undersigned at the below-listed number.

Respectfully submitted,
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